

REMARKS

The Office action dated May 7, 2010 is acknowledged. The Applicants thank the Examiner for entry of the request for continued examination (RCE). Claims 1-9 and 11-30 are pending in the instant application. According to the Office action, each of claims 1-9 and 11-30 are rejected. By the present response, claims 1, 4, 5, 8, 9, 13, 19, 20 and 26 have been amended and claims 7 and 11 have been canceled. Claim 1 has been amended to incorporate the subject matter of claims 7 and 11 and for purposes of clarification. The other claims have been amended for purposes of clarification. Claim 26 has been amended to depend from claim 1 rather than claim 7, which is now canceled. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

Rejection of Claims 1, 2, 5, 11, 12, 17, 22 and 23 under 35 U.S.C. 102(b) / 35 U.S.C.

103(a)

Claims 1, 2, 5, 11, 12, 17, 22 and 23 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,765,348 (Honeycutt), or in the alternative as being obvious over Honeycutt in view of U.S. Patent No. 4,793,366 (Hill). The Examiner states that Honeycutt discloses a device for administration of nicotine to the human body by inhalation (col. 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (col. 1, lines 8-10), wherein the device comprises each and every limitation of the presently claimed invention and that one skilled in the art would have found it inherent that a free base of nicotine which is contained by absorption in a polytetrafluoroethylene element is thus inherently contained in a polymer matrix in a dispersed form

Alternatively, the Examiner states that if the aforementioned is not inherent to one skilled in the art then the teachings of Hill would remedy the deficiency of Honeycutt.

The Examiner states that Hill teaches a device for administration of nicotine to the human body by inhalation with a nicotine preparation comprising a polymer matrix wherein the basic active agent is contained in a dissolved or dispersed form. In this regard, the Examiner's conclusion is that it would have been obvious to one of ordinary skill in the art to provide the device of Honeycutt with a nicotine polymer matrix preparation as taught by Hill in order to provide the advantage of better control of the transfer properties of the basic active agent.

The Applicant respectfully disagrees with the Examiner's assessment of the presently claimed invention in view of Honeycutt. It is respectfully submitted that Honeycutt fails to disclose each and every limitation of the presently claimed invention as the claims are currently amended. Honeycutt does not disclose a device for the administration of basic active agents such as nicotine, wherein the active agents are dissolved or dispersed in a polymer matrix. As pointed out in the previous Office action response, Honeycutt teaches a non-combustible simulated cigarette inhaler device which includes a hollow cylindrical tube having an open air inlet and an opposed open air outlet. Two elements of absorbent air permeable material are located within the hollow tube. The first element of absorbent air permeable material is located across a segment of the transverse cross-sectional area of the tube and is impregnated with a nicotine-free base material. The other element of absorbent air permeable material is located across the remaining segment of the transverse cross-section of the tube, and is impregnated with an acid which is reactive with the free base.

It was also pointed out in the previous Office action response that the term “impregnated” means that the materials of the first and second element are coated or covered with the nicotine free base or acid. Thus, the nicotine free base or acid is absorbed to the surface of the materials of the first and second material. It is submitted that one skilled in the art would recognize that the term “impregnated” does not in any way include the incorporation of either the basic active agent or acid into the materials of the first or second element. Moreover, it is further submitted that the aforementioned is true since those skilled in the art are aware of the fact that, (1) the materials that are used for the first or second element include cotton, cellulose acetate, granulated charcoal, granulated polytetrafluoroethylene (column 2, lines 57-60) and, (2) there is no method described therein for incorporating, i.e., dispersing or merging, the active agent with these polymers.

As noted above, the Examiner argues in the Office action that the basic active agent is absorbed by a polymer element and that this inherently would mean that the basic active agent on some level is present in the polymer matrix to some extent. The Applicants respectfully disagree with this conclusion. First, Honeycutt only discloses that nicotine is present in a liquid or sorbed state in a first element that is made of an air-permeable material (col. 3, line 11). Honeycutt does not specify the mechanism of sorption, i.e., whether it is adsorption or absorption. Adsorption is the process of attraction of atoms or molecules from an adjacent gas or liquid to an exposed solid surface. Absorption, however, is a physical phenomenon or process in which atoms or molecules enter some bulk face such as gas, liquid or solid. Since the first element according to Honeycutt is made up of either cotton, cellulose acetate, granulated charcoal

or granulated polytetrafluoroethylene which are solid materials, it is not possible for a molecule such as nicotine to migrate into these materials to be present in a dissolved or dispersed form. Nicotine can only be present on these solid materials on the surface, but the adsorption of nicotine on the surface of these materials does not inherently disclose, as alleged by the Examiner, that the basic active agent is present in the polymer matrix in a dispersed or dissolved form. It is only present adsorbed on the surface.

Secondly, the presently claimed invention is distinguished from the disclosure of Honeycutt in the kind of materials that are used to form the polymer matrix. The materials according to Honeycutt are selected from the group consisting of cotton, cellulose acetate, granulated charcoal and granulated polytetrafluoroethylene, as discussed above. The presently claimed polymer matrix is made up of either polyethylene, polypropylene, silicone polymers and poly(meth)acrylates. Polytetrafluoroethylene and polyethylene are distinct classes of polymer materials. Accordingly, Honeycutt does not disclose any of the polymer materials that are used in the presently claimed invention.

Thirdly, the presently claimed invention also differs from the disclosure of Honeycutt in the amount of nicotine that is released from the device. Honeycutt is entirely silent about the amount of nicotine that is released from the device disclosed therein. The presently claimed device releases 5 to 250 μg of nicotine when an inspiration process lasts from 1 to 10 seconds and reaches a velocity of inspiration of 0.1 to 1 l/min. The choice of this value should not be considered as discovering an optimum value of a result effective variable which only involves routine skill in the art. As it was not obvious or known at the time of filing the present application which amount is the

optimum amount of nicotine base that can be released from an inhaler device, the inventors of the presently claimed invention had to undertake considerable effort to find out about a suitable amount for administration of nicotine base. Moreover, the present inventors had to discover the assembly of an inhaler device that is suitable for releasing an effective amount of nicotine base. Accordingly, the given release rate of nicotine base in amended claim 1 is not a feature that is obvious in view of Honeycutt.

In view of the above, the subject matter of proposed present claim 1 is not anticipated by Honeycutt since the reference fails to teach each and every limitation of the present claims. Therefore, Honeycutt clearly fails to teach or otherwise disclose every limitation of the present invention as set forth in the present claims and therefore fails to anticipate the present invention. Withdrawal of the anticipation rejection is respectfully requested.

The Applicants now turn to the alternative obviousness rejection of Honeycutt in view of Hill. As discussed above, the subject matter of the presently claimed invention is distinguished from the disclosure of Honeycutt in several aspects, including the arrangement of the nicotine base in dissolved or dispersed from within a polymer matrix, the arrangement of the acid being dissolved or dispersed in a polymer matrix, the choice of suitable polymer materials, and the release rate of nicotine base from the inhaler device. The Hill references fails to make up for any of the numerous deficiencies of Honeycutt that are outlined above. The secondary reference Hill is only directed to the release of nicotine, and as such, one skilled in the art would not consider the Hill reference when faced with the object of providing an inhaler device that simultaneously releases nicotine base and an acid. This is even more true since there is nothing in Hill

that teaches how an inhaler device has to be assembled that releases nicotine base at a sufficient rate to form a salt that comprises both a nicotine base and an acid.

Consequently, one skilled in the art would not consider the reference of Hill as it is not an enabling reference.

Moreover, even if one skilled in the art were to consider the teachings of Hill, the reference would still fail to make up for the numerous deficiencies of Honeycutt as enumerated above. In other words, the combination of teachings of Honeycutt and Hill fail to teach each and every limitation of the presently claimed invention. In particular, Hill fails to teach that a nicotine base is present in dissolved or dispersed form in a polymer matrix. Hill only teaches that a polymer material is loaded with the nicotine-bearing mixture of fluid using any conventional technique for combining a liquid and an absorbent medium including techniques such as dipping the polymer material in a bath of the nicotine-bearing mixture and spraying the nicotine-bearing mixture onto polymer material (col. 5, lines 57-63). However, as discussed above, when nicotine base is merely sprayed onto a polymer material it can only be present in or on the polymer material at the surface. It is not possible for a nicotine base molecule to migrate into a solid polymer material to be finally present in a dissolved or dispersed form. In this respect, it is also noted that Hill is entirely silent about the possibility of an acid being present in dispersed or dissolved form in a polymer matrix.

Furthermore, Hill fails to implicitly or explicitly teach or disclose that the device for the administration of nicotine has to be assembled in a way that nicotine base is released in an amount of 5 to 250 μg .

As Hill does not make up for the numerous deficiencies of Honeycutt, it is clear

that the presently claimed invention is not obvious in view of a combination of teachings of Honeycutt and Hill. Therefore, Honeycutt in view of Hill clearly fails to teach or otherwise disclose every limitation of the present invention as set forth in the present claims and therefore fails to anticipate the present invention. Withdrawal of the alternative obviousness rejection is respectfully requested.

Rejection of Claims 3, 4, 6-9, 13-21 and 24-30 Under 35 U.S.C. 103(a)

Claims 3, 4, 9, 24, 25 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 4,284,089 (Ray). The Examiner states in the Office action that Honeycutt fails to teach the preparations containing a solvent suitable for inhalation. However, the Examiner refers to Ray for teaching a preparation containing water as a solvent, as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22) . Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 6, 7, 8, 14, 26, 28 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt. The Examiner argues that, regarding claim 6, Honeycutt teaches that the chemical balance between volatilized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, the Examiner concludes that it would have been obvious to one skilled in the art that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

The Examiner also argues that, regarding claims 7, 8, 14, 26 and 30, Honeycutt

discloses the claimed invention except for the inspiration duration, velocity, nicotine dose, particle size and negative pressure differential. The Examiner concludes that it would have been obvious to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10) since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claim 28 and 29, the Examiner states in the Office action that Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. The Examiner concludes that it would have been obvious to one skilled in the art to make the entire device out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,400,808 (Turner). The Examiner states that Honeycutt does not disclose the material which is impermeable but argues that Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt of a material as taught by Turner to provide the advantage of a longer shelf life of the contents of the inhaler.

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 726,037 (Ferre). The Examiner states that Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. The Examiner refers to Ferre for teaching an inhaler with separate impermeable compartments (a, c) that have orifices (f) that can be opened or closed. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with sealable compartments as taught by Ferre and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

Claims 15-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,660,169 (Källstrand, et al.). The Examiner argues that Honeycutt discloses the claimed invention except for a part formed by deep-drawing. The Examiner argues that Källstrand, et al. disclose an inhaler device with an upper (1) and bottom part (2) containing a compartment with a peelable seal (Figs. 3a-c) formed by deep-drawing (column 2, lines 11-14). Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with deep-drawn components as taught by Källstrand, et al. in order to provide the advantage of an inexpensive way to manufacture the device.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third,

the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion and various obviousness rejection set forth in the Office action for the numerous deficiencies of Honeycutt (and Hill) discussed above. Honeycutt fails to teach each and every limitation of the presently claimed invention, as discussed in detail above. Moreover, none of the additional cited secondary references make up for any of the numerous deficiencies of Honeycutt (or Hill). Therefore, the combination of Honeycutt with the teachings of any of the additional secondary references, even when considered in view of Hill, fails to teach each and every limitation recited in the present claims.

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Honeycutt alone or in combination with the secondary references, nor would one skilled in the art be motivated to modify Honeycutt to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

Conclusion

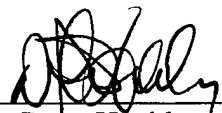
For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if

there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: September 7, 2010

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